K090025

Syneron

510(K) Summary of Safety and Effectiveness

JAN – 8 2010

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

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Name of the Device: Matrix RF Applicator

Predicate Devices: This is a 510(k) submission for the Matrix RF Applicator that is substantially equivalent to the following cleared devices.

- Matrix RF Applicator, manufactured by Syneron, Ltd., and subject of K073572
- Thermage ThermaCool System, manufactured by Thermage and subject of K052936
- Accent, manufactured by Alma Lasers, Ltd., and subject of K070004

Device description: The Matrix RF Applicator is composed of a connector, cable, handpiece and disposable tips. Treatment using the Matrix RF Applicator is based on delivery of bipolar radio frequency to the skin surface via an array of electrode-pins.

Indications for Use: The Matrix RF Applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.

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Conclusion: The overall specifications, principle of operation, performance characteristics of Matrix RF Applicator device have not been changed. Therefore, the additional indication for use of the Matrix RF Applicator device should raise no new issues of safety. The device was found to be effective for the new indication, supporting the additional indication of the device for ablation and resurfacing of the skin for wrinkle treatment.

07/04/2004

Date

Avi Hirshnzon

VP QA and Regulatory Affairs

Syneron Medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Syneron Medical Ltd.
% Mr. Avi Hirshnzon
VP, QA and Regulatory Affairs
Industrial Park
P.O.B. 550
Yokneam Illit, 20692, Israel

JAN - 8 2010

Re: K090025
Trade/Device Name: Matrix RF Applicator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 02, 2009
Received: November 06, 2009

Dear Mr. Hirshnzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K090025

Device Name: Matrix RF Applicator

Indications for Use:

The Matrix RF Applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090025